**Introduction**

Germ cells are cells in a woman’s ovaries and a man’s testicles that can develop into eggs or sperm. Tumors can sometimes start in the germ cells. Most of the time, germ cell tumors grow in a woman’s ovaries or a man’s testicles, but rarely germ cells can move to other parts of the body and grow into tumors in those locations. Surgery, chemotherapy and radiation are often used to treat germ cell tumors. Sometimes, treatment may include a stem cell transplant using the patient’s own cells. Stem cells are collected from the patient’s blood and stored. After the patient receives high-dose chemotherapy, stem cells are given back to the patient. Using a person’s own stem cells is known as an autologous stem cell transplant. Using stem cells from a donor is called an allogeneic transplant. Using donor stem cells to treat germ cell tumors is investigational (unproven) because there is not enough scientific evidence to show that it works for this condition.
Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Single autologous HCT                        | **Single autologous hematopoietic cell transplantation (HCT) may be considered medically necessary as salvage therapy for germ-cell tumors:**  
  • In patients with favorable prognostic factors that have failed a previous course of conventional-dose salvage chemotherapy  
  OR  
  • In patients with unfavorable prognostic factors as initial treatment of first relapse (i.e., without a course of conventional-dose salvage chemotherapy) and in patients with platinum-refractory disease (see **Favorable and Unfavorable Prognostic Factors** below). |
| Tandem or sequential autologous HCT          | **Tandem or sequential autologous HCT may be considered medically necessary for the treatment of testicular tumors either as salvage therapy or with platinum-refractory disease.**                                          |
| Autologous HCT                               | **Autologous hematopoietic cell transplantation (HCT) is considered investigational as a component of first-line treatment for germ-cell tumors.**                                                                 |
| Allogeneic HCT                               | **Allogeneic HCT is considered investigational to treat germ-cell tumors, including, but not limited to use as therapy after a prior failed autologous hematopoietic cell transplantation.**                                     |

## Favorable and Unfavorable Prognostic Factors

The favorable and unfavorable prognostic factors listed next are derived from the current National Comprehensive Cancer Network (NCCN) guidelines and DeVita et al’s textbook Cancer: Principles
Favorable and Unfavorable Prognostic Factors

Patients with favorable prognostic factors include those with a testis or retroperitoneal primary site, a complete response to initial chemotherapy, low levels of serum markers, and low volume disease. Patients with unfavorable prognostic factors are those with an incomplete response to initial therapy or relapsing mediastinal nonseminomatous germ cell tumors.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>38230</td>
<td>Bone marrow harvesting for transplantation; allogeneic</td>
</tr>
<tr>
<td>38232</td>
<td>Bone marrow harvesting for transplantation; autologous</td>
</tr>
<tr>
<td>38240</td>
<td>Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor</td>
</tr>
<tr>
<td>38241</td>
<td>Hematopoietic progenitor cell (HPC); autologous transplantation</td>
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<tr>
<td>38242</td>
<td>Allogeneic lymphocyte infusions</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>S2140</td>
<td>Cord blood harvesting for transplantation, allogeneic</td>
</tr>
<tr>
<td>S2142</td>
<td>Cord blood derived stem cell transplantation, allogeneic</td>
</tr>
<tr>
<td>S2150</td>
<td>Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications including phoresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and posttransplant care in the global definition</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Benefit Application

The following considerations may supersede this policy:

- State mandates requiring coverage for autologous bone marrow transplantation offered as part of National Institutes of Health–approved clinical trials of autologous bone marrow transplantation.

- Some plans may participate in voluntary programs offering coverage for patients participating in National Institutes of Health–approved clinical trials of cancer chemotherapies, including autologous bone marrow transplantation.

Some contracts or certificates of coverage may include specific conditions in which autologous bone marrow transplantation would be considered eligible for coverage.

Evidence Review

Description

Therapy for germ-cell tumors is generally dictated by several factors, including disease stage, tumor histology, site of tumor primary and response to chemotherapy. Patients with unfavorable prognostic factors, incomplete initial responses, and early relapse after initial complete response may be candidates for hematopoietic cell transplantation (HCT).

Background

Hematopoietic Cell Transplantation

HCT refers to a procedure in which hematopoietic stem cells are infused to restore bone marrow function in cancer patients who receive bone-marrow-toxic doses of cytotoxic drugs with or without whole body radiation therapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or from a donor (allogeneic HCT). They can be harvested from bone marrow, peripheral blood, or umbilical cord blood shortly after delivery of neonates. Although cord blood is an allogeneic source, the stem cells in it are antigenically “naïve” and thus are associated with a lower incidence of rejection or graft-versus-host disease. Cord blood is discussed in greater detail in a separate medical policy. (See Related Policies)
Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. However, immunologic compatibility between donor and patient is a critical factor for achieving a good outcome of allogeneic HCT. Compatibility is established by typing of human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the tissue type expressed at the Class I and Class II loci on chromosome 6. Depending on the disease being treated, an acceptable donor will match the patient at all or most of the HLA loci (with the exception of umbilical cord blood).

**Germ-Cell Tumors**

Germ-cell tumors are composed primarily of testicular neoplasms (seminomas or non-seminomatous tumors) but also include ovarian and extragonadal germ-cell tumors (eg, retroperitoneal or mediastinal tumors). Germ-cell tumors are classified according to their histology, stage, prognosis, and response to chemotherapy.

Germ cell tumor histologies include seminoma, embryonal carcinoma, teratoma, choriocarcinoma, yolk sac tumor, and mixed germ-cell tumors. Seminomas are the most common; all other types are collectively referred to as non-seminomatous germ-cell tumors.

Stage is dependent on location and extent of the tumor, using the American Joint Committee on Cancer’s TNM system. TNM stages, modified by serum concentrations of markers (S0-3) when available, are grouped by similar prognoses. Markers used for germ-cell tumors include human beta-chorionic gonadotropin (B-hCG), lactate dehydrogenase (LDH), and alpha fetoprotein (AFP). Pure seminoma does not have elevated AFP levels except for very rare cases with very minimal elevations whereas B-hCG may be elevated in about 20% of seminomas, especially if there is a large tumor burden. Elevations of AFP indicate a non-seminomatous component present. For testicular tumors, Stages IA-B have tumors limited to the testis (no involved nodes or distant metastases) and no marker elevations (S0); Stages IIA-C have increasing size and number of tumor-involved lymph nodes, and at least one marker moderately elevated above the normal range (S1); Stages IIIA-C have distant metastases and/or marker elevations greater than specified thresholds (S2-3).

Germ-cell tumors also are divided into good-, intermediate-, or poor-risk categories based on histology, site, extent of primary tumor, and serum marker levels. Good-risk pure seminomas can be at any primary site, lack marker elevations, and lack non-pulmonary visceral metastases. Intermediate-risk pure seminomas have non-pulmonary visceral metastases with or without elevated hCG and/or LDH. There are no poor-risk pure seminomas. Mixed histology tumors and seminomas with elevated AFP (due to mixture with non-seminomatous components) are
managed as non-seminomatous germ-cell tumors. Good- and intermediate-risk non-seminomatous germ-cell tumors have testicular or retroperitoneal tumors without non-pulmonary visceral metastases, and either S1 (good risk) or S2 (intermediate) levels of marker elevations. Poor-risk tumors have mediastinal primary tumors, or non-pulmonary visceral metastases, or the highest level (S3) of marker elevations.

Therapy for germ-cell tumors is generally dictated by stage, risk subgroup, and tumor histology. Testicular cancer is divided into seminomatous and non-seminomatous types for treatment planning because seminomas are more sensitive to radiation therapy. Stage I testicular seminomas may be treated by orchiectomy with or without radiation or single-dose carboplatin adjuvant therapy. Non-seminomatous stage I testicular tumors may be treated with orchiectomy with or without retroperitoneal lymph node dissection. Higher stage disease typically involves treatment that incorporates chemotherapy. First-line chemotherapy for good- and intermediate-risk patients with higher-stage disease is usually 3 or 4 cycles of a regimen combining cisplatin and etoposide, with or without bleomycin depending on histology and risk group. Chemotherapy is often followed by surgery to remove residual masses. Second-line therapy often consists of combined therapy with ifosfamide/mesna and cisplatin, plus vinblastine, paclitaxel, or etoposide (if not used for first-line treatment). Patients whose tumors are resistant to cisplatin may receive carboplatin-containing regimens. The probability of long-term continuous complete remission diminishes with each successive relapse.

Summary of Evidence

For individuals who have previously untreated germ cell tumors who receive first-line treatment with autologous hematopoietic cell transplantation (HCT), the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The available trials found that autologous HCT as initial therapy for germ cell tumors did not significantly improve outcomes compared with alternative therapy (e.g., standard-dose chemotherapy). Study sample sizes were relatively small and may have been underpowered to detect differences between groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have relapsed or have refractory germ cell tumors who receive autologous HCT, the evidence includes 1 RCT and several case series. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The RCT did not find significant differences in outcomes between autologous HCT plus high-dose chemotherapy and standard-dose chemotherapy. Case series found 3-year overall survival rates that ranged from 55% to 60%; these studies lacked comparison groups. Although the evidence is weak, there is
strong support from external local and national experts in the field to cover autologous HCT in these situations.

For individuals with germ cell tumors who receive tandem or sequential HCT, the evidence includes 1 RCT, several retrospective cohort studies, and a comparative effectiveness review. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. The RCT found a higher rate of treatment-related mortality with sequential HCT than with single HCT. However, 5-year survival outcomes did not differ significantly between groups. Overall, the available studies have included heterogeneous patient populations, in different salvage treatment settings (ie, first vs subsequent salvage therapy), and have lacked a universally accepted prognostic scoring system to risk-stratify patients. Tandem or sequential HCT has not shown benefit in patients with primary mediastinal germ cell tumors. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have germ cell tumors who receive allogeneic HCT, the evidence includes a case report. Relevant outcomes are overall survival, disease-specific survival, and treatment-related mortality and morbidity. There were no RCTs or non-RCTs evaluating allogeneic HCT for germ cell tumors. One 2007 case report described successful treatment of a refractory mediastinal germ cell tumor with allogeneic HCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00432094</td>
<td>Autologous Peripheral Blood Stem Cell Transplant for Germ-Cell Tumors</td>
<td>25</td>
<td>Jan 2017</td>
</tr>
<tr>
<td>NCT00936936</td>
<td>High-dose Chemotherapy for Poor-prognosis Relapsed Germ-cell Tumors</td>
<td>68</td>
<td>Jun 2018</td>
</tr>
</tbody>
</table>

NCT: National clinical trial
Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN) Guidelines

Current National Comprehensive Cancer Network guidelines on testicular cancer (v.1.2017) state that, for patients with unfavorable prognostic features (e.g., incomplete response to first-line treatment), high-dose chemotherapy followed by autologous hematopoietic cell transplant (HCT) is a treatment option. The guidelines do not address the use of tandem or sequential HCT in the treatment of testicular tumors.

American Society for Blood and Marrow Transplantation

In 2015, guidelines by the American Society for Blood and Marrow Transplantation were published on indications for autologous and allogeneic HCT. Recommendations were intended to describe the current consensus on use of HCT within and outside of the clinical trial setting. Recommendations on germ cell tumors are listed in Table 2.

Table 2. ASBMT Recommendations on Allogeneic and Autologous HCT

<table>
<thead>
<tr>
<th>Indications</th>
<th>Allogeneic HCT</th>
<th>Autologous HCT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pediatric</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germ cell tumor, relapse</td>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td>Germ cell tumor, refractory</td>
<td>D</td>
<td>C</td>
</tr>
<tr>
<td><strong>Adult</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germ cell tumor, relapse</td>
<td>N</td>
<td>C</td>
</tr>
<tr>
<td>Germ cell tumor, refractory</td>
<td>N</td>
<td>C</td>
</tr>
</tbody>
</table>

ASBMT: American Society for Blood and Marrow Transplantation; C: clinical evidence available, standard of care; D: developmental (i.e., promising); HCT: hematopoietic cell transplantation; N: not generally recommended.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
Regulatory Status

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation (CFR) title 21, parts 1270 and 1271. Hematopoietic stem cells are included in these regulations.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/09/14</td>
<td>New PR policy replacing 8.01.35, added to Therapy section. Policy developed with literature review through March 5, 2014. Policy statement on tandem or sequential autologous HSCT as medically necessary for the treatment of testicular tumors germ cell tumors either as salvage therapy or with platinum-refractory disease now requires enrollment in a clinical trial.</td>
</tr>
<tr>
<td>02/03/15</td>
<td>Update Related Policies. Remove 8.01.23, 8.01.28 and 8.01.30.</td>
</tr>
<tr>
<td>06/09/15</td>
<td>Annual Review. Policy updated with literature review; no change in policy statements. ICD-9 and ICD-10 diagnosis and procedure codes removed; these were for informational purposes only.</td>
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<tr>
<td>09/01/16</td>
<td>Update Related Policies. Remove 8.01.27 as it was archived.</td>
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<tr>
<td>11/01/16</td>
<td>Annual Review, approved October 11, 2016. Policy updated with literature review through June 14, 2016; references 2, 17, 38, and 46 added. Policy statements unchanged. Removed codes that are transplant benefit related. Codes listed in the policy will be reviewed for medical necessity.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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</tr>
<tr>
<td>04/01/17</td>
<td>Annual Review, approved March 14, 2017. Policy updated with literature review through November 9, 2016; references 9 and 20 added. Changed “hematopoietic stem cell transplantation” to “hematopoietic cell transplantation” per NCCN terminology change. Policy statements unchanged.</td>
</tr>
<tr>
<td>06/09/17</td>
<td>Coding update; updated description for CPT codes 38230, 38240, and 38241.</td>
</tr>
<tr>
<td>08/01/17</td>
<td>Updated title of Related Policy 8.01.511.</td>
</tr>
<tr>
<td>12/01/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
</tbody>
</table>

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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

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  Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
  Email AppealsDepartmentInquiries@Premera.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
- U.S. Department of Health and Human Services
  200 Independence Avenue SW, Room S09F, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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